Background and Importance
Porokeratosis is a rare group of diseases characterized by annular keratotic plaques due to altered skin keratinization. It is associated with mutations in mevalonate pathway, that causes the accumulation of toxic metabolites in the skin and the lack of the end product: cholesterol.

Therapeutic options are limited, due to small number of cases. The dual combination of cholesterol with an HMG-CoA-inhibitor (to avoid accumulation of toxic metabolites) may improve cutaneous lesions.

Aim and Objectives
A 53-year-old male was diagnosed with perianal Porokeratosis ptchotropica (PP) in 2012. He underwent multiple topical treatments: imiquimod, diclofenac, tacalcitol, calcipotriol, calcitriol and photodynamic therapy (PDT), all of them were unsuccessful.

The Pharmacy service was asked to develop cholesterol 2%/lovastatin 2% ointment, based on a series of cases of other forms of porokeratosis, in which this formulation was successful.

Materials and Methods
i) Design and validation of a topical formulation of cholesterol 2%/simvastatin 1%; Since lovastatin was not commercially available as raw material in our setting, the equivalence was made to simvastatin (2:1).

ii) Evaluation of its effectiveness by physician global assessment (PGA) based on clinical appearance and patient adherence and tolerance by pharmacist interview.

Results
1) Ointment formulation
Cholesterol 2%/simvastatin 1% ointment was formulated on a petroleum jelly basis, as it provides a source of lipids to the stratum corneum and helps improve skin barrier function.

- Shelf-life: 6 months
- At room T (25°C)
- Protected from light

2) Patient results
PGA: 3

Dosage regimen
- Twice daily
- 6 months
- Once daily
- 6 months
- 3 days/week

Patient questionnaire
- Compliance: 80-85% (5-6 times/week)
- Tolerability: Any adverse event
- Satisfaction rating: 4.5/5
- Patient-specific results: “The treatment that has worked best to date”

Figure 1. Clinical response after application of the ointment. (A) Phtotropic porokeratosis affecting the gluteus and perianal area before application of the ointment. (B) Results after 6 months (B) and one year (C) after application of simvastatin 1%/cholesterol 2% ointment.

Concluding and Relevance
Cholesterol 2%/simvastatin 1% ointment improved both cutaneous lesions and symptomatology in a single patient with PP that had not improved with previous therapies, showing an adequate safety profile and low cost.